#### §721.11

has submitted a significant new use notice under this part and the notice review period has ended.

- (3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a notice under this part. the manufacturer, importer, or processor must immediately cease distributing the substance to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:
- (i) The manufacturer, importer, or processor has submitted a significant new use notice under this part and the notice review period has ended.
- (ii) The recipient has submitted a significant new use notice under this part and the notice review period has ended.
- (iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.
- (e) Any significant new use notice relating to import of a substance must be submitted by the principal importer.

 $[53~{\rm FR}~28359,~{\rm July}~27,~1988,~{\rm as~amended}~{\rm at}~60~{\rm FR}~34464,~{\rm July}~3,~1995]$ 

# § 721.11 Applicability determination when the specific chemical identity is confidential.

- (a) A person who intends to manufacture, import, or process a chemical substance which is described by a generic chemical name is subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines that the person has a bona fide intent to manufacture, import, or process the chemical substance for commercial purposes.
- (b) To establish a bona fide intent to manufacture, import, or process a chemical substance, the person who intends to manufacture, import, or process the chemical substance must submit the following information in writing to the Document Control Office

(DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: SNUR Bonafide submissions.

- (1) The specific chemical identity of the chemical substance that the person intends to manufacture, import, or process
- (2) A signed statement that the person intends to manufacture, import, or process the chemical substance for commercial purposes.
- (3) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture, import, or process the chemical substance.
  - (4) An elemental analysis.
- (5) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or, if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.
- (c) If an importer or processor cannot provide all the information required in paragraph (b) of this section because it is claimed as confidential business information by the importer's or processor's manufacturer or supplier, the manufacturer or supplier may supply the information directly to EPA.
- (d) EPA will review the information submitted by the manufacturer, importer, or processor under paragraph (b) of this section to determine whether than person has shown a bona fide intent to manufacture, import, or process the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical substance under §710.7(e)(2)(v) of this chapter or the information requested under §720.85(b)(3)(iii) of this chapter.
- (e) If the manufacturer, importer, or processor has shown a bona fide intent to manufacture, import, or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform

the manufacturer, importer, or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies.

- (f) A disclosure to a person with a bona fide intent to manufacture, import, or process a particular chemical substance that the substance is subject to this part will not be considered public disclosure of confidential business information under section 14 of the
- (g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

[53 FR 28359, July 27, 1988, as amended at 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006]

#### §721.20 Exports and imports.

Persons who intend to export a chemical substance identified in subpart E of this part, or in any proposed rule which would amend subpart E of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who import a substance identified in a specific section in subpart E of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification requirements appears at 40 CFR part 707.

[53 FR 28360, July 27, 1988]

### § 721.25 Notice requirements and procedures.

(a) Each person who is required to submit a significant new use notice under this part must submit the notice at least 90 calendar days before commencing manufacture, import, or processing of a chemical substance identified in subpart E of this part for a significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be sub-

mitted on EPA Form 7710-25, and must comply with the requirements of part 720 of this chapter, except to the extent that they are inconsistent with this part 721.

- (b) If two or more persons are required to submit a significant new use notice for the same chemical substance and significant new use identified in subpart E of this part, they may submit a joint notice to EPA. Persons submitting a joint notice must individually complete the certification section of part I of the required notification form. Persons who are required to submit individually, but elect to submit jointly, remain individually liable for the failure to submit required information which is known to or reasonably ascertainable by them and test data in their possession or control.
- (c) EPA will process the notice in accordance with the procedures of part 720 of this chapter, except to the extent they are inconsistent with this part.
- (d) Any person submitting a significant new use notice in response to the requirements of this part 721 shall not manufacture, import, or process a chemical substance identified in subpart E of this part for a significant new use until the notice review period, including all extensions and suspensions, has expired.

[53 FR 28360, July 27, 1988, as amended at 60 FR 16311, Mar. 29, 1995; 75 FR 787, Jan. 6, 2010]

## § 721.30 EPA approval of alternative control measures.

(a) In certain sections of subpart E of this part, significant new uses for the identified substances are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of substances which are identified in such sections, or alternative measures to control worker exposure or environmental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a chemical substance identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination